SUMMARY

futibatinib

LYTGOBI 4 mg,

film-coated tablet

Initial inclusion

Original French opinion adopted by the Transparency Committee on 10 January 2024

The legally binding text is the original French opinion version

Transparency Committee's Conclusions

Clinical Benefit

- Cholangiocarcinoma is a serious condition, which is life-threatening in the short term.
- This is a curative treatment.
- The efficacy/adverse effects ratio is low on account of the lack of robust comparative data with available alternatives as a second-line treatment in particular the FOLFOX chemotherapy regimen (the indirect comparisons provided could not be retained on account of substantial methodological weaknesses), and the additional toxicity in particular the incidence of grade ≥ 3 adverse events (AEs) of 76.7%. Moreover, the onset of serous retinal detachment was identified as a substantial risk in the RMP.
- This is a second- and further-line treatment for the subgroup of patients with locally advanced or metastatic intrahepatic cholangiocarcinoma with fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement, whose disease has progressed after at least one line of systemic treatment, and who are ineligible for FOLFOX chemotherapy, in view of the available therapies.
- **Public health benefit**

In view of:

- the seriousness of the condition and its prevalence;
- the partially met medical need;
- the lack of an additional response to the identified need on account of:
  - the lack of evidence of an additional impact of futibatinib on morbidity-mortality;
  - the lack of robust data on quality of life;
  - the lack of evidence of any impact on delivery of care;
  - the lack of expected additional impact on the care and/or life pathway in the absence of supporting data;

LYTGOBI (futibatinib) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of LYTGOBI (futibatinib) 4 mg is:

- **low for the subgroup of patients with locally advanced or metastatic intrahepatic cholangiocarcinoma with fibroblast growth factor receptor 2 (FGFR2) gene fusion or rearrangement, whose disease has progressed after at least one line of systemic treatment, and who are ineligible for FOLFOX chemotherapy, and at the MA dosage.**
- **insufficient in other contexts covered by the marketing authorisation indication.**

The Committee approves the inclusion of LYTGOBI (futibatinib) 4 mg in the list of covered drugs for outpatients and in the list of covered drugs for inpatients only for the subgroup of patients with locally advanced or metastatic intrahepatic cholangiocarcinoma with fibroblast growth factor receptor 2 (FGFR2) gene fusion or rearrangement, whose disease has progressed after at least one line of systemic treatment, and who are ineligible for FOLFOX chemotherapy.

The Committee disapproves the inclusion of LYTGOBI (futibatinib) 4 mg in the list of covered drugs for outpatients and in the list of covered drugs for inpatients for the other contexts covered by the MA indication.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 100%**

Clinical Added Value

Within the reimbursement scope selected by the Committee:

Taking into account:

- the data from a non-comparative study, and the lack of robust data from indirect comparisons that are difficult to interpret on account of methodological weaknesses;
- the partially met medical need for cases ineligible for the FOLFOX regimen, with PEMAZYRE (pemigatinib) in particular;
- the additional toxicity in particular the incidence of grade ≥ 3 adverse events (AEs) of 76.7%. Moreover, the onset of serous retinal detachment was identified as a substantial risk in the RMP;

the Committee deems that LYTGOBI (futibatinib) 4 mg provides no clinical added value (CAV V) for the treatment of the subgroup of patients with locally advanced or metastatic intrahepatic cholangiocarcinoma with fibroblast growth factor receptor 2 (FGFR2) gene fusion or rearrangement, whose disease has progressed after at least one line of systemic treatment, and who are ineligible for FOLFOX chemotherapy.